

EXHIBIT J



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April 7, 2010

VIA ECF

Hon. Ann Marie Donio, U.S.M.J.
United States District Court for the District of New Jersey
Mitchell H. Cohen Federal Building & U.S. Courthouse
1 John F. Gerry Plaza
Camden, NJ 08101

**Re: AstraZeneca v. Apotex and AstraZeneca v. Breath
Consolidated Civil Action N. 3:08-cv-1512 (RMB)(AMD)**

Dear Judge Donio:

We write on behalf of Defendants Apotex, Inc. and Apotex Corp. (collectively, "Apotex") in advance of the April 8th status conference to request your Honor's assistance regarding some issues that have arisen concerning the improper withholding of highly relevant discovery by Plaintiffs AstraZeneca LP and AstraZeneca AB (collectively, "AstraZeneca" or "Plaintiffs").

After Plaintiffs' lawsuit against Apotex was consolidated into Plaintiffs' existing lawsuit against Breath, and Plaintiffs and Apotex subsequently agreed to an initial exchange of documents, Plaintiffs produced to Apotex in July 2009 over 500,000 pages of documents that had already been produced in the Breath litigation.¹ In early January, Apotex served Plaintiffs with some discovery requests, including both interrogatories and some document requests to insure that Apotex received all relevant documents, some of which Apotex did not find in Plaintiffs' July production.² However, Plaintiffs have refused, and continue to refuse, to provide responses to certain of these requests. Though Apotex disagrees with many positions Plaintiffs have taken, we write to request the Court's assistance with respect to a select number of particularly important items.

Additionally, Apotex recently discovered that Plaintiffs have improperly withheld documents based on an incorrect theory of attorney-client privilege. Because attempts to resolve this matter have been unsuccessful, we also seek the Court's assistance in this regard.

¹ Exhibit A (Letter dated July 9, 2009 from Derek M. Kato to David W. Aldrich). Plaintiffs also periodically supplemented this production.

² Exhibit B (Letter dated January 8, 2010 from David W. Aldrich to Derek M. Kato).

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Plaintiffs' Improper Withholding of the Labeling Instructions for Its Own Products that Bear Directly On the Invalidity of the Once-Daily-Dosing Patents

In this case, Plaintiffs assert that the sale of Apotex's generic version of Pulmicort Respules®, a nebulizable budesonide inhalation suspension ("BIS"), will infringe the claims of Plaintiffs' patents that relate to the administration of nebulized budesonide "not more than once per day." The labeling instructions that will accompany Apotex's product reference only "twice daily" dosing, as Apotex has removed all references to "once daily" dosing from its label because of these patents. However, Plaintiffs assert that Apotex's product will still infringe these patents because Apotex's label contains safety language indicating that patients should be "titrated down" to the lowest effective dose. Apotex contends that, if such "titration down" language really amounts to an instruction to administer the product "once daily" (as Plaintiffs assert), then these patents are invalid over prior art that contains similar language.

Interrogatory No. 11

Interrogatory No. 11 requests information that directly addresses this central issue. Specifically, it requests:

For each country in which a nebulizable BIS Product has been sold by or on behalf of Plaintiffs, identify (i) whether any instructions to titrate down to the lowest effective dose accompanied any sale of that product prior to December 31, 1997, and (ii) the specific language of those instructions.³

Plaintiffs provided no information in response to this interrogatory, instead objecting to the extent that it sought information outside of the U.S.⁴ Apotex explained that this was improper, as instructions accompanying products sold prior to December 31, 1997 would constitute prior art whether in the U.S. or not.⁵ In response, Plaintiffs assert: "Any possible relevance of such 'instructions' would be far outweighed by the burden associated with searching for and collecting" this information.⁶

This position is completely unreasonable. Plaintiffs' whole infringement case for these patents is based on "titration down" language. There is *no* information *more relevant* than the information requested by this interrogatory. The interrogatory is narrowly tailored to *Plaintiffs'* products, to a specific type of product (nebulizable BIS), and in time (prior to Dec. 31, 1997, when such instructions would qualify as prior art). As admitted by Plaintiffs, they sold a nebulizable BIS

³ Exhibit C (AstraZeneca's Response to Apotex's First Set of Interrogatories (1-18)) at 14.

⁴ *Id.* at 15.

⁵ Exhibit D (Letter dated March 9, 2010 from David W. Aldrich to Brian Kao) at 1.

⁶ Exhibit E (Letter dated March 22, 2010 from Michael S. Burling to David W. Aldrich) at 2.

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product in a number of countries prior to December 31, 1997. *Id.* Plaintiffs should be required to answer this directly relevant and narrowly tailored interrogatory immediately.

Documents Request Nos. 14-16

Document Request Nos. 14-16 each recite a list comprising Pulmicort Respules® and other budesonide products sold by Plaintiffs, seeking particular labeling documents for these products. Specifically, they request the *first government approved* label and/or package insert for these products (No. 14), the first label and/or package insert *to accompany* these products (No. 15), and any *revised* versions of the labels and/or package inserts *that accompanied* these products (No. 16).⁷ Plaintiffs indicated they already produced documents responsive to this request, apparently limiting their response to the U.S. Pulmicort Respules® product.⁸ Apotex explained that these documents are relevant to invalidity,⁹ but Plaintiffs again maintain that any “possible relevance” is outweighed by the burden of collecting these documents.¹⁰

These requests are very specific, seeking only labels and/or package inserts. For the reason discussed above, the language of these labels go directly to the very heart of this case, and Plaintiffs should be required to produce these documents immediately.

Plaintiffs’ Improper Withholding of Information Concerning Its Own Prior Art Sterile Budesonide Products that Is Highly Relevant to the Invalidity of the Sterilization Patent

The other patent that Plaintiffs have asserted against Apotex’s nebulized BIS product relates to Plaintiffs’ alleged invention of a way to sterilize budesonide. However, it appears that Plaintiffs sold sterile budesonide products years before this patent. Such products would have been accompanied by publications concerning the product, which are highly relevant to the invalidity of this patent.

Interrogatory No. 16

Interrogatory No. 16 simply seeks information that would clarify exactly *what* sterile budesonide products Plaintiffs sold *when*. Specifically, it requests:

⁷ Exhibit F (AstraZeneca’s Response to Apotex’s First Set of Requests for Production of Documents and Things (1-61)) at 13-15.

⁸ *Id.*

⁹ Exhibit G (Letter dated March 15, 2010 from Roy D. Gross to Brian Kao) at 3.

¹⁰ Exhibit H (Letter dated April 2, 2010 from Michael S. Burling to Roy D. Gross) at 3.

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For each country in which a product containing budesonide has been sold by or on behalf of Plaintiffs prior to November 14, 1997, identify the date on which a sterile version of that product was first sold.¹¹

Again, Plaintiffs provided basically no information in response to this interrogatory, first objecting to the extent that it sought information about products outside the U.S. or products that are not "inhalation suspensions," and then uselessly confirming that they did not sell a sterile "budesonide inhalation suspension product" prior to November 14, 1997.¹² Again, Apotex explained that there is no basis to restrict Plaintiffs' response in these ways.¹³ In response, Plaintiffs again assert that any "possible relevance" of such information is "far outweighed by the burden associated with AstraZeneca searching for and collecting such information," and again limit their response to sterile "inhalation" products.¹⁴

Prior sterile budesonide products are directly relevant to the invalidity of Plaintiffs' sterilization patent. The interrogatory is narrowly tailored to *Plaintiffs'* products and in time (prior to Nov. 14, 1997, when published material about these products would qualify as prior art). Though Plaintiffs suggest there is a substantial burden, they do not explain why. Indeed, it is believed there are actually few products responsive to this interrogatory, which seeks only dates. Apotex is simply seeking information regarding what sterile budesonide products Plaintiffs sold prior to Nov. 14, 1997. AstraZeneca should be required to answer this directly relevant and narrowly tailored interrogatory immediately.

Documents Requests Nos. 43 & 44

These requests seek documents concerning Preferid®, a previous product of Plaintiffs that was purportedly a sterile budesonide product. Specifically, Document Request No. 43 seeks:

All documents and things concerning the sterilization requirements for the manufacture and/or sale of Preferid®, including the Preferid® product marketed in Scandinavian countries.¹⁵

Document Request No. 44 seeks:

All documents and things concerning labeling and package insert information for Preferid®, including the Preferid® product marketed in Scandinavian countries.¹⁶

¹¹ Exhibit C at 17.

¹² *Id.* at 17-18.

¹³ Exhibit D at 2.

¹⁴ Exhibit E at 2-3.

¹⁵ Exhibit F at 30.

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Plaintiffs simply objected and indicated they would not produce documents responsive to these requests.¹⁷ Apotex explained that these documents relate to a sterile budesonide product and are therefore relevant to Apotex's invalidity contentions.¹⁸ Plaintiffs do not address this explanation, but continue to vaguely assert that these requests are unduly burdensome and irrelevant.¹⁹

As noted above, these documents are highly relevant to the invalidity of the sterilization patent. The requests ask only for documents concerning the sterility requirements and for the labels/package inserts, and thus, are not unduly burdensome. Plaintiffs have no basis for refusing to produce these documents and should be required to do so immediately.

Plaintiffs' Improper Withholding of Communications with Swedish In-House Employees

1. Background

On January 15, 2010, Plaintiffs sent a letter to all counsel of record, indicating that certain documents in its productions are protected by the attorney-client privilege and/or work product immunity and were inadvertently produced and requesting the return of these documents.²⁰ Included in this letter was a series of pages bearing bates numbers AZ1343541-AZ134346.

On January 19, 2010, Apotex requested clarification on whether AZ1343541-AZ134346 is actually protected by the attorney-client privilege and/or work product immunity.²¹ On January 20, 2010, Plaintiffs corrected their request and indicated that only AZ1343541 is allegedly protected by the attorney-client privilege, since it reflects communications to counsel (James Peel).²² Upon receiving this clarification, Apotex sent Plaintiffs a follow-up letter on February 2, 2010 asking whether James Peel was an in-house employee in Sweden at the time of the communication in question and whether the communication in question related to the prosecution of Swedish patent application SE19970004186.²³ Both points were eventually confirmed by Plaintiffs on February 22, 2010.²⁴ That same day, Apotex advised AstraZeneca that communications with in-house counsel in

¹⁶ *Id.* at 31.

¹⁷ *Id.*

¹⁸ Exhibit G at 4.

¹⁹ Exhibit H at 5.

²⁰ Exhibit I (Letter dated January 15, 2010 from Hassen A. Sayeed to Amy D. Brody and David W. Aldrich).

²¹ Exhibit J (Letter dated January 19, 2010 from Roy D. Gross to Hassen A. Sayeed).

²² Exhibit K (Letter dated January 20, 2010 from Michael S. Burling to Roy D. Gross).

²³ Exhibit L (Letter dated February 2, 2010 from David W. Aldrich to Michael S. Burling).

²⁴ Exhibit M (Letter dated February 22, 2010 from Michael S. Burling to David W. Aldrich).

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Sweden relating to a Swedish patent application are not protected by an attorney-client privilege and requested that AstraZeneca immediately produce all documents that have been improperly withheld on this basis.²⁵

Plaintiffs rebuffed this request in a letter dated February 25, 2010, in which they cited two cases to support the position that the attorney-client privilege applies to protect AZ1343541 from disclosure.²⁶ However, as Apotex subsequently explained to Plaintiffs, these cases are inapposite.²⁷ Further, though it does not have the burden to do so, Apotex provided an explanation and various references demonstrating that communications with in-house employees in Sweden are not protected by an attorney-client privilege. Apotex again requested that Plaintiffs produce all communications withheld on this basis, and Apotex requested a teleconference to discuss the matter if Plaintiffs continued to maintain that this privilege exists. Plaintiffs have ignored Apotex's requests.

Further, on March 10, 2010, Apotex received Plaintiffs' confidential privilege log, which indicates that Plaintiffs appear to have improperly withheld many additional documents on this basis.

2. It is AstraZeneca's Burden to Establish that the Attorney-Client Privilege Applies to Its Communications

As noted by Apotex in its letter of March 10, 2010, it is AstraZeneca's burden to establish that the attorney-client privilege exists in each country for which it makes a privilege claim, not Apotex's burden that it does not. As courts have noted, "[t]he burden of proving privilege rests on the party resisting disclosure." *Glaxo, Inc. v. Novopharm, Ltd.*, 148 F.R.D. 535, 538 (E.D.N.C. 1993) (citing *Fischer v. United States*, 425 U.S. 391, 96 S.Ct. 1569 (1976)). See also *U.S. v. Landof*, 591 F.2d 36, 38 (9th Cir. 1978). When foreign law is involved, "[t]he burden is on the party asserting the privilege to provide the court with the applicable foreign law, and demonstrate that the privilege applies to the documents it seeks to exclude from discovery." *Smithkline Beecham Corp. v. Apotex Corp.*, 193 F.R.D. 530, 535 (N.D. Ill. 2000). See also *McCook Metals LLC v. Alcoa Inc.*, 192 F.R.D. 242, 256 (N.D. Ill. 2000); *In re Rivastigmine Patent Litigation*, 237 F.R.D. 69 (S.D.N.Y. 2006) (rejecting assertion of privilege in Swedish documents).

Plaintiffs have not met this burden. Moreover, for the reasons discussed below, Plaintiffs *cannot* meet this burden, since Swedish law does not protect communications between in-house counsel and company employees.

²⁵ Exhibit N (Letter dated February 22, 2010 from David W. Aldrich to Michael S. Burling).

²⁶ Exhibit O (Letter dated February 25, 2010 from Michael S. Burling to David W. Aldrich).

²⁷ Exhibit P (Letter dated March 10, 2010 from David W. Aldrich to Michael S. Burling).

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3. The Attorney-Client Privilege In Sweden Does Not Cover Communications Between In-House Counsel and Other Company Employees Relating to Prosecution of a Swedish Patent Application

It is well understood that there is no attorney-client privilege for in-house counsel in Sweden.^{28,29,30,31,32,33} The attorney-client privilege that exists under Swedish law is conferred by Chapter 36, Section 5 of the Swedish Procedural Code, under which the attorney-client privilege in Sweden exists only between clients and members of the Swedish Bar Association (bearing the title "advokat"). Only lawyers in private practice are allowed membership in the SBA; in-house counsel are not permitted to be members.³⁴ This is a basic tenet of Sweden's legal profession with the purpose of insuring that advokats are not subject to undue influence.³⁵

4. AstraZeneca Should Produce AZ1343541 and All Other Documents Withheld On a Similar Basis

In its letters of January 20, 2010 and February 22, 2010 (*see* Exhibits K& M), Plaintiffs clearly confirmed that AZ1343541 was a communication drafted to James Peel, an in-house attorney at AstraZeneca who was involved in the preparation of Swedish patent application SE19970004186. Since James Peel is not an "advokat" and was an in-house lawyer at AstraZeneca, such communications are not protected by an attorney-client privilege. Accordingly, this document should be produced. Similarly, all other documents improperly withheld by AstraZeneca based upon Plaintiffs' improper reliance on attorney-client privilege for in-house counsel in Sweden

²⁸ Exhibit Q (http://www.lexmundi.com/images/lexmundi/PDF/AttyClient/2009Update/Attorney_Client_Update8.09_Main_Document.pdf, page 134).

²⁹ Exhibit R (Lordi, *The Attorney-Client Privilege in the European Union and Italy: Time for a Change*, 11 Duq. Bus. L.J. 47, 51 (2008)).

³⁰ Exhibit S (Hill, *Disparate Positions of Confidentiality and Privilege Across National Boundaries Create Danger and Uncertainty for In-House Counsel and Their Clients*, Widener Law School Studies, Research Paper No. 08-65. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1147659).

³¹ Exhibit T (Fish, *Regulated legal professionals and professional privilege within the European Union, the European Economic Area and Switzerland, and certain other European jurisdictions*, CCBE, 2004, available at http://elixir.bham.ac.uk/Free%20Movement%20of%20Professionals/Links_docs/fish_report_en.pdf, pages 46-47).

³² Exhibit U (*The European Lawyer*, April 2008, page 11, *The Privilege Patchwork*).

³³ Exhibit V (Davainis, *Are European In-House Counsel Covered by the Attorney-Client Privilege*, *International Journal of Baltic Law*, Vol. 1, No. 4, (December 2004), page 16).

³⁴ Exhibit W (http://www.advokatsamfundet.se/Documents/Advokatsamfundet_eng/From%20Scandinavian%20Studies%20of%20Law.pdf).

³⁵ *Id.*

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should be produced. This includes communications to and from Mr. James Peel,³⁶ as well as all similar communications concerning in-house attorneys and legal staff in Sweden. Apotex requests that Plaintiffs be compelled to produce these documents immediately.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Christina L. Saveriano". The signature is written in a cursive, flowing style.

CHRISTINA L. SAVERIANO

³⁶ Document Nos. 6, 8-13, 19-26, 30-32, 34-38, 41-43, 50-56, 59-72, 90-97, 99-101, 113-114, 118-119, 121, 123-133, 149-153, 156-157, 173-176, 182-183, 185-187, 194, and 248 on Plaintiffs' privilege log.